Fax-on-Demand
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Item: 6071

JUSTIFICATION STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

a. TITLE: **MAXIMUM RESIDUE LIMIT PETITIONS FOR PESTICIDES ON FOOD/FEED AND NEW INERT INGREDIENTS**

OMB NO. 2070-0024

EPA NO. 0597. 07

b. Characterization

The use of pesticides to increase crop production often results in pesticide residues in or on the crop. To protect the public health from unsafe pesticide residues, the Environmental Protection Agency (EPA) sets limits on the nature and level of residues permitted. While EPA is authorized to set pesticide Maximum Residue Limits (MRLs), the Food and Drug Administration (FDA) is responsible for their enforcement. Food or feed commodities found to contain pesticide residues in excess of established MRLs are considered adulterated, and are subject to seizure.

This information collection request (ICR) covers all requests for MRLs, or exemptions from the requirement of a MRL, for both active and inert ingredients in pesticides. The type of data that is required to be submitted is dependent on the type of MRL that is sought. There are five types of MRL petitions that may be submitted and EPA may request the submission of data and/or other relevant information to assist it in its review and in setting the appropriate MRLs. The five types are as follows:

1. Temporary MRL (or an exemption from the requirement for a temporary MRL) to permit sale of commodities containing residues resulting from authorized experimental use of an unregistered pesticide. In the absence of a such a MRL or exemption, all such commodities must be destroyed. Because exposure is limited by the nature of the experimental use, the range of data required to support a temporary MRL is generally less than for a permanent MRL.

2. Permanent MRL (or an exemption from the requirement for a permanent MRL) for residues which would result from a pesticide use registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

3. Permanent MRL (or an exemption from the requirement for a permanent MRL) petitioned by third parties for residues resulting from registered uses, usually on minor crops for which the pesticide registrant is unwilling to seek a MRL. When minor crops are involved, the range of data requirements is adjusted to be commensurate with the extent of pesticide use.

4. MRLs for other ingredients in pesticides, such as solvents, baits, dust carriers, fillers, wetting or spreading agents, propellants, emulsifiers, etc.

5. MRLs for residues on commodities which are not grown in the United States, and therefore for which there is no U.S. registrant (i.e., import MRLs).

When necessary, EPA will also establish an MRL as part of the Agency's review of a state application for an emergency exemption for pesticides under section 18 of FIFRA. However, this information collection does not cover state submitted MRL data pursuant to section 18 activities since EPA collects relevant state MRL data under the ICR entitled, "*Application and Summary for an Emergency Exemption for Pesticides*" (OMB# 2070-0032).

It is EPA's responsibility to ensure that the maximum residue levels likely to be found in or on food/feed are safe for human consumption through a careful review and evaluation of residue chemistry and toxicology data. In addition, EPA must ensure that adequate enforcement of the MRL can be achieved through the testing of submitted analytical methods. Once the data are deemed adequate to support the findings, EPA will establish the MRL or grant an exemption from the requirement of a MRL.

There are no forms associated with this information collection.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

MRLs for pesticide residues in food or feed are set under the authority of sections 402, 406, and 408, of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended. Regulations covering MRLs are contained in Title 40 of the Code of Federal Regulations (CFR) Parts 177 and 180. Actual listings of individual MRLs by chemical are found in 40 CFR Parts 180, 185 and 186. Copies of pertinent statutes and regulations are attached.

2(b). Use/Users of the Data

The Food Quality Protection Act of 1996 (FQPA) directs the Agency to consider aggregate exposures from dietary and non-occupational sources when assessing the risks of a chemical and setting MRLs. In addition to dietary exposure, such sources as drinking water and residential lawn care use need to be considered. EPA must make the statutory determination that the resulting pesticide residues in food or feed will result in a reasonable certainty of no harm effects of human health from aggregate exposure through dietary, non-occupational, and drinking water routes of exposure before establishing the MRL.

EPA uses the data collected to set the MRL. Risk Managers review all regulatory aspects of each petition, coordinate scientific review of supporting data, and prepare the public notices and rules necessary to establish a MRL or exemption. Residue Chemists review the residue data submitted to determine if the nature and magnitude of likely residues are adequately characterized, and ensure that acceptable analytical methods are available to enforce the proposed MRL. The Agency's toxicologists review the toxicology data to evaluate the potential effects of the residues on health, and assess the cumulative dietary significance of residues of the pesticide on other crops and commodities, and the likelihood of exposure to particularly sensitive sub-populations. As a result of these reviews, EPA is able to make the statutory determination that the resulting pesticide residues in food or feed will not cause unreasonable adverse dietary effects on human health.

3. THE RESPONDENTS AND THE INFORMATION REQUESTED

3(a). Respondents/SIC Codes

The three-digit Standard Industrial Classification codes assigned to the businesses and other institutions participating in this program are **286** (Industrial Organic Chemicals) and **287** (Agricultural Chemicals). Under the North American Industrial Classification System (NAICS) the code is **325320** (Pesticide and other Agricultural Chemical Manufacturing). Respondents may include pesticide manufacturing companies, Interregional Research Project No.4 (IR-4) petitioners, and third party registrants.

3(b). Information Requested

(I) Data Items

In addition to a cover letter and fee, a MRL petition must include the following eight parts:

1. Identify chemical	The name, chemical identity, and composition of the pesticide chemical. If the pesticide chemical is an ingredient of a pesticide, the complete quantitative formula of the resulting pesticide product should be submitted. The submission of this information does not restrict the application of any MRL or exemption granted to the specific formula(s) submitted.
2. Chemical use	The amount, frequency, and time of application of the pesticide chemical.
3. Safety reports	Include reports of investigations made with respect to the safety of the pesticide chemical. These reports should include, when necessary, detailed data derived from appropriate animal or other biological experiments in which the methods used and the results obtained are clearly set forth.
4. Residue test results	The results of tests on the amount of residue remaining, including description of the analytical method used. (See section 180.34 for further information about residue tests.)
5. Residue removal	Practicable methods for removing residue that exceeds any proposed MRL.
6. Propose MRL	Proposed MRLs for the pesticidal chemical if MRLs are proposed.
7. Grounds for petition	Reasonable grounds in support of the petition.
8. Summary	An informative summary of the petition or application, including a summary of the supporting data, information, accompanying rationales, and a statement providing permission to publish such summary. This summary should indicate how approval of the petition will meet the statutory determination required of "reasonable certainty of no harm."

The data compiled for the eight categories should be submitted as separate sections, suitably identified. If data has already have been submitted with an earlier application, the present petition may incorporate it by reference. The petition must be submitted in triplicate, consistent with PR Notice 86-5. The petitioner shall show that he/she has registered or has submitted an application for the registration of a pesticide under section 3 of FIFRA.

(ii) Respondent Activities

In order for a MRL to be established, allowing for distribution, sale and use, of a pesticide product, a respondent (petitioner) must undertake the following activities:

Review regulations	Read applicable FFDCA regulations/CFR citations;
Conduct tests	conduct any toxicological or residue chemistry studies and develop analytical methods required in order to provide the EPA with the data necessary to make a decision to accept or reject a MRL petition and review the requested data for accuracy/appropriateness;
Prepare correspondence	generate petition correspondence, including preparing a informative summary to be published in the Federal Register;
Review Agency comment	read notice of any petition deficiency;
Respond to Agency comment	submit supplemental petition, or request that petition be filed as submitted; and
Maintain records	store, file and maintain the information.

Changes as a Result of the Passage of the FQPA

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. Effective upon signature, the new statute significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act. The new amendment establishes a strong health based safety standard for setting MRLs for pesticides in food. The FQPA requires that MRLs be set at a level to ensure that there be "a reasonable certainty that no harm will result from aggregate exposure." Among other things, FQPA requires EPA to consider a number of new factors when setting such MRLs or registering pesticide products, including: 1) special protection for infants and children; 2) aggregate of exposure and risk from foods and other known sources, such as drinking water and household pesticide use; and 3) consideration of common mechanisms of toxicity (some chemicals have different molecular structures but cause deleterious effects in the same manner).

Since FQPA passed, EPA is applying this tough, new standard to all MRLs for newly-registered chemicals and food uses. In addition, FQPA has set a schedule for reassessing all 10,000 existing MRLs under this new standard by 2006. The new law did not provide for a phase-in period for many of the new requirements which had not

previously been a part of EPA's risk assessment process. EPA has not changed the informational requirements of this ICR from the previous ICR. But while EPA does not require registrants to submit any additional information under this ICR, the new FQPA provisions requires EPA to consider additional information in order to make the necessary regulatory decisions. Therefore, petitioners, who submitted data to the Agency prior to passage of FQPA, are encouraged to supplement their original submissions with additional information. Respondents submitting new petitions may want to submit supplemental information to the Agency even without a requirement to do so. To allow for the most efficient processing and review of MRL petitions, the Agency has provided a description of the types of information that EPA considers helpful in the Appendices to Pesticide Registration (PR) Notice No. 97-1. If supplemental information is not submitted, the Agency must rely on previously submitted data, if applicable, or on broad or default assumptions when considering the factors listed. As a result, favorable action on a petition decision may be significantly delayed.

PR 97-1 applies to most applicants with registration applications, non-crop-destruct experimental use permit applications, and MRL or MRL exemption petitions pending within the Agency. It also applies to most future applicants seeking new or amended pesticide registrations and all actions involving synthetic chemicals, antimicrobial, biochemical and microbial pesticides. However, the notice does not apply to applicants seeking fast track "me-too" registrations or amendments not involving new uses.

4. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

4(a) Agency Activities

Upon receipt of a MRL petition, EPA performs the following activities:

Log	Log petition and associated fee.
Review petition	Screen petition, fee, and supporting data for completeness and acceptability; resolve any deficiencies with petitioner.
Prepare Federal Register notice	Upon acceptance, publish notice of filing in Federal Register.
Review data	Review supporting residue chemistry, toxicology data and other assessments received.
Test analytical methods	Test proposed analytical methods in EPA laboratories, if they are new or modified.

Integrate review	Integrate data reviews and determine adequacy; resolve any deficiencies with petitioner.
Prepare decision document	Prepare decision document, Federal Register Notice, and rule establishing MRL(s) or exemption.
Maintain records	Record all actions and decisions in official records.

4(b). Collection Methodology

Specific studies submitted as part of petition are catalogued and archived as they are received. When the Agency review is complete, the remaining portions of the petition record, including correspondence subsequent to filing and all reviews, notices, and other materials created by EPA in the course of its review, are catalogued and archived. All petition materials are retained permanently.

4(c). Small Entity Flexibility

At times, small entities seek a MRL or an exemption from the requirement of a MRL for residues resulting from registered uses. These actions are usually initiated for minor crop uses for which the pesticide registrant is unwilling to seek a MRL or for residues on commodities which are not grown in the United States and therefore for which there is no U.S. registrant, such as import MRLs. In such cases, the EPA can reduce the burden and cost to small entities by adjusting the range of data requirements to be commensurate with the extent of pesticide use. The Agency also uses this type of regulatory flexibility to set MRLs for residues on commodities which are not grown in the United States.

4(d). Collection Schedule

Not applicable. This is not a scheduled collection. A petition is required only once for each raw or processed commodity on which the pesticide is used.

5. NON-DUPLICATION, CONSULTANTS, AND OTHER COLLECTION CRITERIA

5(a). Non-duplication

To avoid overlap between the requirement of developing data in support of a MRL petition and the development of data for a FIFRA registration, EPA allows the use of data required to support a MRL petition that are already archived in EPA records to be used as part of a FIFRA registration of a pesticide to be used in a like manner and in the same use pattern.

5(b). Consultations

In order to reduce the petition processing time, pre-filing conferences may be conducted to identify and resolve possible problem issues on petitions. However once a petition is filed, consultation and/or dialogue between the petitioner and the EPA occurs on an informal, ongoing "as needed" basis. Most dialog occurs at the time of a re-submission to correct a deficiency and the subsequent review of the petition data. Our experience has been that when any sort of a problem arises, whether it is technical, administrative, or other, the participants have ample opportunity and do not hesitate to contact the Agency.

5(c). Effects of Less Frequent Collection

Not applicable. This activity is conducted only once per "event." Consequently, there is no way that the EPA can reduce the frequency of the collection and not violate the requirements established by law.

5(d). General Guidelines

Due to the requirement for permanent retention of supporting chemistry and toxicological data included in petitions, the PRA guideline that records need be retained for no more than three years is exceeded.

5(e). Confidentiality

Trade secret or confidential business information (CBI) is frequently submitted to the EPA in this program because submissions usually include the manufacturing process, product formulation, and supporting data. When such information is provided to the Agency, the information is protected from disclosure under FIFRA section 10. CBI data submitted to the EPA is handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Security Manual.

5(f). Sensitive Questions

Not applicable. No information of a sensitive or private nature is requested in this information collection activity.

6. ESTIMATING BURDEN AND COST OF THE COLLECTION

6(a). Estimating respondent (Petitioner) Burden

A total of 150 petitions are projected to be received in FY 1993. Annually, registrants may spend approximately 216,300 labor hours or $123,111 in labor costs to comply with all of the requirements for residue petitions.

The paperwork burden is a portion of the total annual labor burden estimated at 455 hours. The total estimated respondent paperwork burden to comply with this information collection activity is 68,220 hours.

ANNUAL PETITIONER BURDEN/COST ESTIMATES

	BURDEN HOURS (per year)				
ACTIVITIES	Mgmt. $123/hr	Tech. $83/hr	Cler $38/hr	Hour	Costs
a) Review FFDCA regulations CFR citations	20	40	20	80	6,540
b) Conduct Field Trial	210	900	24	1,134	101,442
c) Prepare Petition	35	25	96	156	10,028
d) Read Notice of any petition deficiency	1	1	1	3	244
e) Prepare response	2	36	10	48	3,614
f) Maintain information	1	8	12	21	1,243
Paperwork Burden Activities *	81	250	124	455	35,425
TOTAL BURDEN	269	1,010	163	1,442	123,111

* Paperwork and record keeping activities include items c, d, and e, and 20% of b. These numbers were calculated using a lotus spread sheet; therefore, the numbers are rounded.

ANNUAL BURDEN: 1,442 Total hours x 150 Petitioners= 216,300 hours
ANNUAL PAPERWORK BURDEN: 455 Total hours x 150 Petitioners=68,250 hours

6(b). Estimating Petitioner Cost.

The total annual cost to respondents (projected at 150) petitioning for MRLs for pesticides on food/feed and/or for new inerts is estimated at $18,466,650. For respondents, the value of labor per hour for management, technical, and clerical is **$123, $83, and $38**, respectively.[1]

ANNUAL COSTS[2]:

(a) Management - 269 hours x $123 x 150 applicants = $ 4,963,050
(b) Technical - 1,010 hours x $ 83 x 150 applicants = $ 12,574,500
(c) Clerical - 163 hours x $ 38 x 150 applicants = $ 929,100

Total $18,466,650

These labor burden estimates represent the average time and costs. Some MRL petitions will require less effort and more complicated petitions will require more of each. The analysis assumes that one respondent will generate the data for a given petition. If a consortium takes responsibility for the petition, the burden and cost will be distributed across members of the consortium.

6(c). Estimating Agency Burden and Cost

The Agency needs to process, review and document their evaluation of the MRL petitions. Each year, the Agency may spend 345,000 hours for 150 petitions in labor burden. Estimates for the Agency's burden are provided below.

[1] Information Collection Request for the Proposed Regulations for Plant-Pesticides under FIFRA and FFDCA, Office of Pesticide Programs, U.S. EPA, March 28, 1994.

[2]The was an error in the calculation of the petitioner's annual cost in the previous ICR and previous cost estimates did not include paperwork burden. The annual cost should have been the following:

a) Management - 269 hours x $114 x 150 = $459,990
b) Technical - 1,010 hours x $77 x 150 = $11,665,500
c) Clerical - 163 hours x 35 x 150 applicants= $855,750
Total $12,981,240

ANNUAL AGENCY BURDEN/COST ESTIMATES

	BURDEN HOURS (per year)			TOTAL	
COLLECTION ACTIVITIES	Mgmt. $84/hr.	Tech. $61/hr	Cler. $29/hr	Hours	Costs
a) Log petition and associated fee	0	8	0	8	448
b) Screen petition request for completeness	1	2	0	3	206
c) Draft and publish Federal Register notice	1	4	0	5	328
d) Review Residue Chemistry and Toxicology data;	261	1,742	3	2,006	128,273
e) Verify new analytical methods in EPA Lab. and resolve any deficiencies	34	223	1	258	16,488
f) Integrate Data Reviews	6	0	2	8	562
g) Prepare decision document and Federal Register Notice	4	4	2	10	638
h) Record actions in official records.	0	0	2	2	58
Paperwork Burden Total	70	409	7	486	31,032
TOTAL BURDEN	307	1983	10	2,300	147,041

*These numbers were calculated using a lotus spread sheet; therefore the numbers are rounded.

(a) Management - 307 hours x $84 x 150 petitioners = $ 3,868,200
(b) Technical - 1,983 hours x $61 x 150 petitioners = $18,144,450

(c) Clerical - 10 hours x $29 x 150 petitioners = $ 43,500
TOTAL= $22,0556,150

2. OTHER ANNUAL AGENCY COSTS:
(a) **FEDERAL REGISTER** mailing costs = $13,000
(b) Electronic mail costs = $ 6,500
TOTAL = $19,500

6(d). Bottom Line Hours And Costs / Master Table

MASTER TABLE

	TOTAL	
	Hours	Costs
Petitioner: Burden/Cost Estimates	1,442	$18,466,650
Agency: Burden/Cost Estimates/petition	2,300	$22,056,150

6(e). Reasons for Changes In Respondent (Petitioner) Burden

With the exception of cost increases for labor rates, there are no changes to the registrant burden from the currently approved ICR. The increase in cost reflects updated current labor values (1998 values). Wage rates for both petitioner and agency increased. For petitioner rates increased for management from $114 to 123, technical from $77 to $83 and clerical from $ 35 to $38 and for the agency rates increased are for management from $76 to $84, technical from $55 to $61 and clerical from $25 to $29.

6(f). Burden Statement

The annual "respondent" (petitioner) burden for the **MRL Petitions On Food/Feed And New Inert Ingredients** program is estimated to average 1442 hours per petition, including time for: processing, compiling and reviewing requested data and generating petition; and storing and maintaining petition data. No person is required to respond to a collection of information unless it displays a currently valid OMB control number.

Comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to should be sent to Chief, Regulatory Information Division, Mail Code 2136, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Include the OMB control number “OMB 2070-0024" on any correspondence.

The following attachments are not available as part of this electronic file.

ATTACHMENTS FOR THE JUSTIFICATION STATEMENT

1. Attachment A: sections 402, 406, 408, and 409 of the FFDCA.
2. Attachment B: 40 CFR Parts 180.7 through 180.41
3. Attachment C: FIFRA section 3.
4. Attachment D: PR Notice 97-1

Attachment A

Sections 402, 406, 408, and 409 of the Federal Food, Drug, and Cosmetic Act

Attachment B

40 CFR Parts 180.1 through 180.41

Attachment C

Section 3 of Federal Insecticide, Fungicide, and Rodenticide Act

Attachment D

PR Notice 97-1